

## CLAIMS

*Sub A1*

1. An oral pharmaceutical formulation comprising an inhibitor compound of the ileal bile acid transport (IBAT inhibitor compound) and a pharmaceutically acceptable carrier, wherein the formulation is designed to deliver the IBAT inhibitor compound in the ileum.
2. The oral pharmaceutical formulation according to claim 1, wherein the formulation is designed to deliver the IBAT inhibitor compound in the ileum by release in one or more parts of the body selected from the distal jejunum and proximal ileum, and/or directly in the ileum.
3. The formulation according to claim 1, wherein the carrier is designed to deliver the IBAT inhibitor compound in the ileum.
4. The formulation according to claim 1, wherein the carrier is designed to release the IBAT inhibitor compound in the distal jejunum and in the proximal ileum.
5. The formulation according to any one of the claims 1 to 4, wherein the carrier is designed to give a minimum release of the IBAT inhibitor compound in the upper part of the small intestine.
6. The formulation according to any one of claims 1 to 4, wherein the pharmaceutical formulation is a delayed release formulation.
7. The formulation according to claim 6, wherein the formulation provides a lagtime of about 0.5 - 2 hours after emptying the stomach.

8. The formulation according to claim 7, wherein the IBAT inhibitor compound is released during the first hour after the lagtime.

*Sally AD* 5  
9. The formulation according to claim 6, wherein release of the IBAT inhibitor compound from the delayed release formulation is triggered by the pH differences between the jejunum and ileum.

10. The formulation according to any one of claims 1 to 9, wherein the IBAT inhibitor compound is a low permeability drug as defined in the Biopharmaceutical Classification System FDA.

11. The use of a pharmaceutical formulation comprising an IBAT inhibitor compound with targeted delivery in the gastro-intestinal tract according to any one of the claims 1 to 10 to reduce systemic exposure.

12. The use of a pharmaceutical formulation comprising an IBAT inhibitor compound with targeted delivery in the gastro-intestinal tract according to any one of the claims 1 to 10 to enhance the therapeutic effect.

20 13. The use of a pharmaceutical formulation according to any one of the claims 1 to 10 in the treatment of hypercholesterolemia.

25 14. The use of a pharmaceutical formulation according to any one of the claims 1 to 10, in the manufacture of a medicament for the prophylactic or therapeutic treatment of hypercholesterolemia.

*Sally AD* 30 15. A method for prophylactic or therapeutic treatment of a subject suffering from, or susceptible to, hypercholesterolemia, which method comprises administering to the subject a pharmaceutical formulation designed according to any one of claims 1 to 10.

16. A pharmaceutical formulation for simultaneous, separate or sequential administration in the prophylactic or therapeutic treatment of hypercholesterolemia, which formulation comprises an IBAT inhibitor compound and a bile acid binder.

5 17. The pharmaceutical formulation according to claim 16, wherein the IBAT inhibitor compound is a low permeability drug as defined in claim 10.

10 18. The pharmaceutical formulation according to claim 16, wherein the bile acid binder is a resin.

15 *Surf Act* 19. The pharmaceutical formulation according to claim 18, wherein the bile acid binder is in a formulation with colon release.

20 20. The use of a pharmaceutical formulation according to any one of claims 16 - 19 in the treatment of diarrhoea during therapy comprising an IBAT inhibitor compound.

25 21. The use of a pharmaceutical formulation according to any one of the claims 16 to 20, in the manufacture of a medicament for the prophylactic or therapeutic treatment of hypercholesterolemia.

20 *Surf Act* 22. A method for prophylactic or therapeutic treatment of a subject suffering from, or susceptible to, diarrhoea during therapy comprising an IBAT inhibitor compound, which method comprises administering to the subject a pharmaceutical formulation designed according to any one of claims 15 to 18.

25 23. The use of a bile acid binder as prophylaxis or in the treatment of diarrhoea during therapy comprising an IBAT inhibitor compound.

*Add A6*

*add*  
*B4*